REMARKS

Claims 1-5 are pending in the instant application. No new matter has been added. Applicants respectfully request reconsideration of the restriction requirement in view of the following remarks.

Claims 1-5 have been subjected to a Restriction Requirement under 35 U.S.C. §121 and §372 as follows:

Group I, claims 1 and 3, drawn to a method for inhibiting or reducing a proinflammatory response in a diseased cell of the respiratory tract comprising contacting the cell with an agent that increases ceramide levels in the cell;

Group II, claim 2, drawn to a method for preventing acute respiratory inflammation comprising administering an agent which increases ceramide levels;

Group III, claim 4, drawn to a method for inducing an inflammatory response in a cell comprising contacting a cell with an agent that increases the levels of ceramide in the cell; and

Group IV, claim 4, is drawn to a method for preventing or reducing a respiratory tract infection comprising administering to a subject at risk an agent which increases ceramide levels. It is noted that while claim 4 is referred to, claim 5 is drawn to a method for preventing or reducing a respiratory tract infection. Therefore, Applicants will assume for the sake of facilitating the prosecution of this application that the Examiner intended to refer to claim 5 in Group IV.

The Examiner suggests that the inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The Examiner

acknowledges that the technical feature shared by the Groups in the instant case is an agent that increases ceramide levels. It is suggested, however, that because Maurer et al. (1999) *J. Natl. Cancer Inst.* 91:1138-46) teach that N-(4-Hydroxyphenyl)-retinamide increases ceramide, this element cannot be a special technical feature.

It is further suggested that the application contains claims directed to more than one species of the generic invention which are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The Examiner requires the election of a single species of an agent that increases ceramide levels.

Applicants respectfully disagree and traverse this restriction requirement and election of species. The Examiner bears the burden of presenting at least a *prima facie* case of anticipation. *In re King*, 801 F.2d at 1327, 231 USPQ at 138-39; *In re Wilder*, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970).

The present invention is directed to methods of increasing ceramide levels in cells of the respiratory tract and modulating inflammatory responses. While Maurer et al. teach that N-(4-hydroxyphenyl)retinamide statistically significantly increases the level of intracellular ceramide and levels of reactive oxygen species in two neuroblastoma cell lines (see abstract), the Examiner has not articulated how this constitutes a *prima facie* teaching or suggestion of increasing ceramide levels in cells of the respiratory tract and modulating inflammatory responses. In so far as the cells and outcome of the method of Maurer et al. are distinct from the subject matter of the instant claims, this reference cannot be held to anticipate or make obvious the

present invention. See *In re Swinehart,* 439 F.2d 210, 169 USPQ 226 (CCPA) 1971); *In re Caldwell*, 138 USPQ 243 (CCPA 1963); *Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987)("so that" functional clause of claim renders reference non-anticipating); MPEP §2173.05(g). Accordingly, unity of invention exists and it is respectfully requested that this restriction requirement be reconsidered and withdrawn.

Moreover, Applicants respectfully traverse the required election of species in this case. In particular, in so far as each of the cited species is an agent that increases ceramide levels, the search of each species within the genera is co-extensive and no serious burden would be incurred by the Examiner in searching and examining the genera. In contrast, the prosecution of each of the disclosed species in each Group of inventions separately will pose a substantial economic burden on Applicants. Therefore, reconsideration of this species election is respectfully requested.

In so far as the asserted lack of unity of invention is based upon art that is not relevant to the claimed invention, Applicants respectfully contend that this restriction requirement and election of species is not proper. However, in an earnest effort to be responsive, Applicants hereby elect to prosecute Group I, claims 1 and 3, drawn to a method for inhibiting or reducing a proinflammatory response in a diseased cell of the respiratory tract comprising contacting the cell with an agent that increases ceramide levels in the cell, with traverse.

Applicants also elect fenretinide as the species of agent that increases ceramide levels, with traverse.

Respectfully submitted,

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